



#11/P.T.
PATENT 6/6
Docket No. 377882001720
Elect.

CERTIFICATE OF MAILING BY "FIRST CLASS MAIL"

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to:
Mail Stop Non-Fee Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on May 30, 2003.

Rhea Amid
Rhea Amid

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In the application of:

Gary VAN NEST, Stephen TUCK,
Karen L. FEARON and Dino DINA

Examiner: T. Gibbs

Group Art Unit: 1635

RECEIVED
JUN 04 2003
TECH CENTER 1600/2900

Serial No.: 09/927,884

Filing Date: August 10, 2001

For: IMMUNOMODULATORY
FORMULATIONS AND METHODS
FOR USE THEREOF

RESPONSE TO RESTRICTION REQUIREMENT

Mail Stop Non-Fee Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

This is in response to the Office Action dated May 1, 2003 (Paper No. 10) which sets forth a restriction requirement for pending claims 1-79 in the above-identified application. A response to this action is due June 1, 2003. Accordingly, this response is timely filed.



RECEIVED
JUN 04 2003
TECH CENTER 1600/2900

ELECTION OF INVENTION

Claims 1-79 are pending in this application. Restriction has been required as between the following allegedly distinct groups of inventions:

Group I (claims 1-15, 18-25, 28-29, 56-70 and 73-77): drawn to an immunomodulatory polynucleotide/microcarrier (IMP/MC) complex comprising a polynucleotide comprising an immunostimulatory sequence (ISS) linked to a biodegradable microcarrier (MC), and a kit comprising said immunomodulatory polynucleotide/microcarrier (IMP/MC) complex, classifiable in class 536, subclass 24.3.

Group II (claims 1, 9, 12-17, 20, 26-27, 71-72, 76 and 78-79): drawn to an immunomodulatory polynucleotide/microcarrier (IMP/MC) complex comprising a polynucleotide comprising an immunostimulatory sequence (ISS) linked to a biodegradable microcarrier (MC), and a kit comprising said immunomodulatory polynucleotide/microcarrier (IMP/MC) complex, wherein said complex further comprises an antigen, classifiable in class 536, subclass 24.1

Group III (claims 30-51 and 54-55): drawn to a method of modulating an immune response in an individual comprising administering to an individual a composition comprising an immunomodulatory polynucleotide/microcarrier (IMP/MC) complex comprising a polynucleotide linked to a biodegradable microcarrier (MC), classifiable in class 435, subclass 4; and

Group IV (claims 30, 44, 47-50 and 52-53): drawn to a method of modulating an immune response in an individual comprising administering to an individual a composition comprising an immunomodulatory polynucleotide/microcarrier (IMP/MC) complex comprising a polynucleotide linked to a biodegradable microcarrier (MC), wherein said composition further comprises an antigen, classifiable in class 435, subclass 7.22.

Applicants hereby elect Group I (claims 1-15, 18-25, 28-29, 56-70 and 73-77), with traverse. Applicants expressly reserve their right under 35 U.S.C. § 121 to file a divisional application directed to the nonelected subject matter during the pendency of this application, or an application claiming priority from this application.

As an initial matter, Applicants respectfully point out that the claims all recite a nonbiodegradable microcarrier. Throughout the Office Action, the microcarrier is referred to as biodegradable. Applicants also respectfully point out that the claims separated into the Groups II and IV do not conform with the description given for each group. In Group II, claims 1, 9, 11-15, 20 and 76 do not recite that the complex further comprises an antigen. In Group IV, claims 30, 44 and 47-50 do not recite that the composition further comprises an antigen. Applicants respectfully request that the Examiner correct the listing of claims in these groups should the restriction requirement be upheld with respect to any of the groups.

In support of the restriction between Groups I and II, the Examiner states that the groups are unrelated because they employ different molecules so that independent searches of the prior art would be required.

Applicants respectfully disagree. The claims of the two groups are related by a genus-species relationship and a search of the genus (Group I) would encompass the search of the species (Group II).

Further, Applicants respectfully traverse the classification differences of Groups I and II. The classification definitions of the Office list Group I (class 536, subclass 24.3) as involving probes for detection of specific nucleotide sequences or primers for synthesis of DNA or RNA and Group II (class 536, subclass 24.1) as involving noncoding sequences which control transcription or translation processes. Applicants submit that the claims are directed to immunomodulatory polynucleotide/microcarrier complexes and do not appear to fall under these

classifications. Applicants respectfully submit that the Examiner has not provided adequate explanation for distinguishing the classification of these two groups.

In support of the restriction between Groups III and IV, the Examiner also states that the groups are unrelated because they employ different molecules so that independent searches of the prior art would be required. Again, Applicants respectfully disagree. The claims of the two groups are related by a genus-species relationship and a search of the genus (Group III) would encompass the search of the species (Group IV).

Further, Applicants respectfully traverse the classification differences of Groups III and IV. The classification definitions of the Office list Group III (class 435, subclass 4) as involving processes in which there is a measurement or test of a material which contains an enzyme or microorganism or processes in which a material containing an enzyme or microorganism is used to perform a measurement or test, and Group IV (class 435, subclass 7.22 indented under subclass 4) as involving a measurement or test involving antigen-antibody binding, specific binding protein assay or specific ligand-receptor binding assay. Applicants submit that the claims are directed to methods of modulating an immune response comprising administering an immunomodulatory polynucleotide/microcarrier complex and do not appear to fall under these classifications. Applicants respectfully submit that the Examiner has not provided adequate explanation for distinguishing the classification of these two groups.

Applicants also traverse the separation of the claims of Groups I/II and III/IV as allegedly separate invention. The product of the Group I/II claims is an immunomodulatory polynucleotide/microcarrier (IMP/MC) complex and the Group III/IV claims are drawn to a method of modulating an immune response comprising administering an IMP/MC complex. The Examiner states that "the immunomodulatory polynucleotide/microcarrier (IMP/MC) complex of Groups I and II can be used as a hybridization probe, which is a materially different process than a method of modulating an immune response in an individual comprising administering to an

individual a composition comprising an immunomodulatory polynucleotide as in Groups III and IV." Office Action, page 5. Applicants respectfully point out that the claims of Groups III and IV recite administration of the IMP/MC complex, not simply an immunomodulatory polynucleotide. Applicants also note that the Examiner has provided no support for the assertion that the IMP/MC complex can be used as a hybridization probe. Applicants request that the Examiner support the assertion that the product (Group I/II) and the method of using the product (Group III/IV) are distinct inventions or withdraw the requirement to separate groups (M.P.E.P. §806.05(h)).

Should the Examiner uphold the restriction requirement with respect to Groups I/II and III/IV and the product claim is subsequently found allowable, Applicants reserve the right to request rejoinder of withdrawn process claims which include all the limitations of the allowable product claim for examination (M.P.E.P. §821.04).

CONCLUSION

Applicants request reconsideration of the restriction requirement and examination of the elected subject matter on the merits.

In the unlikely event that the transmittal letter is separated from this document and the Patent Office determines that an extension and/or other relief is required, Applicants petition for any required relief including extensions of time and authorizes the Assistant Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket no. 377882001720. However, the Assistant Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Respectfully submitted,

Dated: May 30, 2003

By:



Karen R. Zachow

Registration No. 46,332

Morrison & Foerster LLP
3811 Valley Centre Drive, Suite 500
San Diego, California 92130
Telephone: (858) 720-5191
Facsimile: (858) 720-5125



Please type plus sign inside this box → ☐

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

PTO/SB/21 (08-00)

Approved for use through 10/31/2002. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

Application Number	09/927,884
Filing Date	August 10, 2001
First Named Inventor	Gary VAN NE
Group Art Unit	1635
Examiner Name	T. Gibbs
Attorney Docket Number	377882001720

Total Number of Pages in This Submission

7

ENCLOSURES (check all that apply)

- | | | |
|---|--|---|
| <input type="checkbox"/> Fee Transmittal Form | <input type="checkbox"/> Assignment Papers
(for an Application) | <input type="checkbox"/> After Allowance Communication
to Group |
| <input type="checkbox"/> Fee Attached | <input type="checkbox"/> Drawing(s) | <input type="checkbox"/> Appeal Communication to Board of
Appeals and Interferences |
| <input checked="" type="checkbox"/> Amendment/Reply | <input type="checkbox"/> Licensing-related Papers | <input type="checkbox"/> Appeal Communication to Group
(Appeal Notice, Brief, Reply Brief) |
| <input type="checkbox"/> After Final | <input type="checkbox"/> Petition | <input type="checkbox"/> Proprietary Information |
| <input type="checkbox"/> Affidavits/declaration(s) | <input type="checkbox"/> Petition to Convert to a Provisional
Application | <input type="checkbox"/> Status Letter |
| <input type="checkbox"/> Extension of Time Request | <input type="checkbox"/> Power of Attorney, Revocation
Change of Correspondence Address | <input checked="" type="checkbox"/> Other Enclosure(s)
(please identify below) |
| <input type="checkbox"/> Express Abandonment Request | <input type="checkbox"/> Terminal Disclaimer | Return Receipt Postcard |
| <input type="checkbox"/> Information Disclosure Statement | <input type="checkbox"/> Request for Refund | |
| <input type="checkbox"/> Certified Copy of Priority
Document(s) | <input type="checkbox"/> CD, Number of CD(s) _____ | |
| <input type="checkbox"/> Response to Missing Parts/
Incomplete Application | Remarks | |
| <input type="checkbox"/> Response to Missing Parts
under 37 CFR 1.52 or 1.53 | | |



25225

PATENT TRADEMARK OFFICE

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm or Individual Name	MORRISON & FOERSTER LLP Karen Zachow - 46,332
Signature	<i>Karen R Zachow</i>
Date	May 30, 2003

I hereby certify that this correspondence is being deposited with the U.S. Postal Service with sufficient postage as First Class Mail, in an envelope addressed to: Mail Stop Non-Fee Amendment, Commissioner for Patents, P O Box 1450, Alexandria VA 22313-1450, on the date shown below.

Dated: 5-30-03

Signature: *Rhea Amid* (Rhea Amid)

1635
RECEIVED
JUN 04 2003
TECH CENTER 1600/2900